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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/981,958	10/16/2001	Joseph J. Florio	A01P1073	7296

36802 7590 04/20/2005

PACESETTER, INC.
15900 VALLEY VIEW COURT
SYLMAR, CA 91392-9221

EXAMINER

FOREMAN, JONATHAN M

ART UNIT PAPER NUMBER

3736

DATE MAILED: 04/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/981,958	FLORIO ET AL.	
	Examiner	Art Unit	
	Jonathan ML Foreman	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 January 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above claim(s) 2,6,8-18,20 and 22-37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-5,7,19,21 and 38-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1, 3 – 5, 19 and 38 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S.

Patent No. 6,714,823 to De Lurgio et al.

3. In reference to claims 1, 3 – 5, 19 and 38, De Lurgio et al. discloses an implantable lead system (Figures 3 and 4) including a lead body (32) for placement in the coronary sinus region (Col. 3, lines 46 – 48), the lead body (32) having at least one tip electrode (52; Col. 8, line 6) positioned at a distal end of the lead body, the distal end of the lead body including a distal tip (38), the lead further having a lumen (36) extending the length of the lead and communicating with an aperture in the distal tip (Col. 6, lines 45 – 49); and a device (42) dimensioned for insertion within the lumen (Col. 7, lines 12 – 15), the device including a main body formed of wire (Col. 7, lines 23 – 24); a steering knob (14) secured to a proximal extremity of the main body; and a flexible distal portion (44) formed of a wire coil separate from the main body secured to a distal extremity of the main body (Col. 7, lines 23 – 24), the main body having a length such that, with the main body of the device substantially completely advanced within the lead, the flexible distal portion of the device projects distally from the aperture in the distal tip of the lead body (Figure 8; Col. 8, lines 11 – 21). The combined length of the main body of the device and the flexible distal portion of the device is slightly longer than the lead body (Figure 2).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 7 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,714,823 to De Lurgio et al. as applied to claims 5 and 19 above, and further in view of U.S. Patent No. 5,746,701 to Noone.

In reference to claims 7 and 21, De Lurgio et al. discloses a guiding member (Figure 4) having a main body and a flexible portion comprising a wire coil, but fails to disclose the wire coil having an outer diameter smaller than that of the main body. However, Noone discloses a guiding member having a main body (101) and a flexible distal portion comprising a wire coil (106; Col. 7, lines 2 – 3), where the outer diameter of the wire coil is smaller than that of the main body (Figure 10). It would have been obvious to one having ordinary skill in the art to modify the wire coil as disclosed by De Lurgio et al. to have an outer diameter smaller than that of the main body as taught by Noone in order to increase the flexibility of the distal portion relative to the main body.

Claims 39 and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,714,823 to De Lurgio et al. as applied to claims 1 and 19 above.

In regards to claims 39 and 40, De Lurgio et al. discloses the combined length of the main body and the flexible distal portion being longer than the lead body (Figure 2). However, De Lurgio et al. fails to disclose the combined length being about 5 to 15 cm longer than the lead body. It would have been an obvious matter of design choice to modify the combined length of the main

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body and the flexible distal portion as disclosed by De Lurgio et al., since applicant has not disclosed that using a combined length of about 5 to 15 cm longer than the lead body provides any advantage, or solves a stated problem, or is used for any particular purpose. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the combined length as taught by De Lurgio et al. or the claimed length of about 5 to 15 cm in claim(s) 39 and 40 because both lengths perform the same function of guiding a lead through a patient's vasculature. Furthermore, a change in the size of a prior art device is a design consideration within the skill of the art. *In re Rose*, 220 F.2d 459, 105 USPQ 237 (CCPA 1955).

Response to Arguments

6. Applicant's arguments filed 1/26/05 have been fully considered but they are not persuasive. Applicant asserts that De Lurgio et al. fails to disclose or suggest that the combined length of the main body and the flexible portion of the device is slightly longer than the lead body. However, the Examiner disagrees. De Lurgio et al. clearly shows the combined length of the main body and the flexible portion being longer than the lead body (Figure 8; Col. 8, lines 11 – 21). The use of "slightly longer" in claims 1 and 19 is terminology of relative degree, which has no basis of comparison. For this reason, it is considered broad and relatively unlimited. The Examiner asserts that the combined length of the main body and the flexible portion of the device as disclosed by De Lurgio et al. is "slightly longer" than the lead body.

Conclusion

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the

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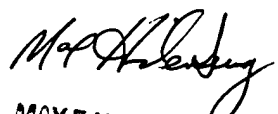
mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan ML Foreman whose telephone number is (571)272-4724. The examiner can normally be reached on Monday - Friday 8:00 am - 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571)272-4726.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


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